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FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCI ATTORNEY'S DOCKET NUMBER TRANSMITTAL LETTER TO THE UNITED STATES 294652US0PCT DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (If known, see 37 CFR 1.5) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/EP05/03144 March 24, 2005 March 24, 2004 TITLE OF INVENTION 8-HYDROXY-5-[(-HYDROXY-2-[[(1R)-2-(4-METHOXYPHENYL)-1-METHYLETHYL] AMINO] [ETHYL]-2(1H)-QUINOLINONE MONOHYDROCHLORIDE IN CRYSTALLINE FORM AND THE PROCESS FOR ITS PREPARATION APPLICANT(S) FOR DO/EO/US Fausto PIVETTI, et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). If the declaration is in a language other than the English language, it is accompanied by an English translation. The translation is accurate (37 CFR 1.69) An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. A copy of the International Preliminary Examination Report (PCT/IPEA/409). A copy of the International Search Report (PCT/ISA/210). Items 13 to 23 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. b. Cited References 6 c. Statement of Relevancy d. List of Related Cases. PTO-1449 An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). Other items or information: Notice of Priority/Annexes to International Preliminary Examination Report (Amended Pages 11-12)

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| 4 0 / 5 0 3 | O. (If known, see | 37 CFR 1.5) | PCT/EP05/ | | DIN INC. | 294652US0PC | |
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| The following fees | | | 11 01721 007 | 00111 | | CALCULATIONS | PTO USE ONLY |
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| | | | | | \$300 | \$300.00 | |
| 25. Examination fee If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations\$200 | | | | | \$200.00 | | |
| 26. Search fee If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority\$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB\$400 All other situations\$500 | | | | | \$400.00 | | |
| TOTAL OF | 24, 25 AND 26 = | = | | | | \$900.00 | |
| sequence listing | or computer pro | ogram listing | s filed in paper over 10 g filed in an electronic r or fraction thereof. | - | | | |
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| or declaration at CLAIMS | NUMBER F | | nent of the national sta | ge (37 CFR 1. RATE | | \$130.00 | |
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| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | | \$1,030.00 \$ | | |
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| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | | | | \$ | | |
| Petition fee of \$1,500.00 for Petition to Revive (37 CFR 1.137 (b)). | | | | | | \$ | |
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| be included on this form. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. | | | | | | | |
| SEND ALL CORRESP | | | • | | | Survh | Per la |
| CUSTOMER NUMBER SIGNATURE | | | | E | | or Sachar | |
| 22850 Norman F | | | F. Ob | • | n No. 34,423 | | |
| Tel. (703) 413-3000 Fax. (703) 413-222 | | | | 24,618 | | | |
| (OSMMN 1/06) | | | | REGISTRAT | TION NUI | MBER | |

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294652US0PCT Docket No.

IAP9'Rec'd PCT/PTO 20 SEP 2006

IN RE APPLICATION OF: Fausto PIVETTI, et al.

SERIAL NO: New U.S. PCT Application Based on PCT/EP05/03144

FILED:

Herewith

FOR:

8-HYDROXY-5-[(-HYDROXY-2-[[(1R)-2-(4-METHOXYPHENYL)-1-METHYLETHYL] AMINO] [ETHYL]-

2(1H)-QUINOLINONE MONOHYDROCHLORIDE IN CRYSTALLINE FORM AND THE PROCESS FOR ITS

PREPARATION

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

Transmitted herewith is an amendment in the above-identified application.

- No additional fee is required
- ☐ Small entity status of this application under 37 C.F.R. §1.9 and §1.27 is claimed.
- Additional documents filed herewith: PCT Transmittal Letter/Credit Card Payment Form for \$1030.00/Application Data Sheet/Notice of Priority/Information Disclosure Statement/PTO-1449/International

Search Report/References Cited(6)/International Preliminary Examination Report/ Annexes to International Preliminary Examination Report Amended Specification

The Fee has been calculated as shown below:

| CLAIMS | CLAIMS REMAINING | | HIGHEST NUMBER PREVIOUSLY PAID | NO. EXTRA CLAIMS | | RATE | | CALCULATIONS |
|------------------|-----------------------------|---|---|---------------------------------|---|-------|--------|--------------|
| TOTAL | 7 | MINUS | 20 | 0 | x | \$50 | = | \$0.00 |
| INDEPENDENT | 2 | MINUS | 3 | 0 | х | \$200 | = | \$0.00 |
| APPLICATION SIZE | | MINUS | 100 | 0 (each addtl. 50 sheets) | x | \$250 | = | \$0.00 |
| | | ☐ MULTII | PLE DEPENDE | NT CLAIMS | + | \$360 | = | \$0.00 |
| | TOTAL OF ABOVE CALCULATIONS | | | | | | \$0.00 | |
| | | ☐ Reduction by 50% for filing by Small Entity | | | | | \$0.00 | |
| | | TOTAL | | | | | \$0.00 | |

| Α | check in | the amount | of \$0.00 i | s attached |
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- ☐ Credit card payment form is attached to cover the fees in the amount of **§0.00**
- Please charge any additional Fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.136, and any additional fees required under 37 C.F.R. §1.136 for any necessary extension of time may be charged to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

word Sochas

Norman F. Oblon

Registration No. 24,618

Customer Number

Tel. (703) 413-3000 Fax. (703) 413-2220 (OSMMN 05/03)

Surinder Sachar

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